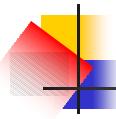


Kathy LaBeau, Network Director
Pacific Northwest Laboratory Medicine Sentinel Monitoring Network

Presentation to CLIAC – September 12, 2002



- Snapshot of testing in 2001/2002
  - What tests are being ordered?
  - Where are tests being performed?
  - How is the genetic testing laboratory chosen?

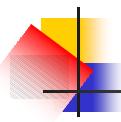


#### Washington State database

- WA Medical Test Site (MTS) Program
  - CLIA-exempt state program
  - More detail about genetic tests than CLIA database
    - Molecular
    - Biochemical
    - Cytogenetic
    - Maternal serum AFP



- 13 of 716 moderate/high complexity labs (1.8%) perform genetic testing
  - 12/13 molecular
  - 6/13 cytogenetic
  - 2/13 biochemical



### Genetic testing in Washington

- 6 research labs
  - Providing results for patient care
- 4 hospitals (university & children's)
- 2 independent labs (1 hospital-based)
- 1 State public health lab (newborn screening)
- 85% are accredited by private organization
  - CAP, AABB, ASHI

### Genetic testing in Washington

- 11 of 716 moderate/high complexity labs (1.5%) perform maternal serum AFP
- Genetic testing accounts for 0.4% of total volume of testing in Washington's moderate/high complexity labs
- 0.37% of which is newborn screening



- Lab Medicine Sentinel Monitoring Network
  - Voluntary participation by 600+ laboratories
    - Waived, PPMP, moderate, high complexity
    - POL, hospital, independent labs
    - Alaska, Idaho, Oregon, Washington
  - Questionnaire sent to 330 moderate & high complexity labs in January 2002
  - 204 respondents Genetic testing orders

### Questionnaire respondents

|        | Questionnaire respondents | All network participants | All labs in<br>Pacific NW |
|--------|---------------------------|--------------------------|---------------------------|
|        | N = 204                   | N = 330                  | N = 1539                  |
| AK (%) | 9                         | 9                        | 6                         |
| ID (%) | 19                        | 19                       | 16                        |
| OR (%) | 22                        | 22                       | 32                        |
| WA (%) | 50                        | 49                       | 46                        |

### Questionnaire respondents

|                    | Questionnaire respondents N = 204 | All network participants N = 330 | All labs in Pacific NW N = 1539 |
|--------------------|-----------------------------------|----------------------------------|---------------------------------|
| Urban/Rural<br>(%) | 54/46                             | 56/44                            | 68/32                           |
| POL/Hosp/IL (%)    | 59/31/9                           | 59/31/10                         | 73/17/10                        |
| Accredited (%)     | 32                                | 33                               | 30                              |



#### Network questionnaire results

- 53% of respondents handled orders for molecular genetic tests in previous 3 months (October - December 2001)
  - 66% of hospitals
  - 58% of independent (reference) labs
  - 46% of physician office labs

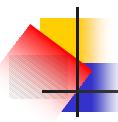
# What tests are most commonly ordered?

- 1) Factor V Leiden Thrombophilia
- 2) Fragile X Syndrome
- 3) Hemochromatosis
- 4) Cystic Fibrosis
- 5) Hemoglobin S

- 6) BCR/ABL Translocation
- 7) BRCA-1 or BRCA-2
- 8) Huntington Disease
- 9) Prader-Willi Syndrome
- 10) Y Chromosome Detection

## On-site testing

- 2% of the network respondents performed molecular genetic testing on-site
  - 3 independent, 1 hospital
  - All urban
  - All accredited

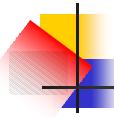


### Send-out testing

- 62% sent orders to their reference lab, who in turn decided where the test would be performed
- 7% sent orders directly to the genetic testing lab
- 31% did some combination of these

# How is the genetic testing laboratory chosen?

- Of 95 responses:
  - 39 % Information from reference lab (37%) or Internet resource about reference labs (2%)
  - 39 % Information from health care provider
    - Genetic counselor (12%)
    - Patient's provider (12%)
    - Medical geneticist (10%)
    - Neurologist, oncologist, pathologist, etc (5%)
  - 8 % Do not know
  - 4 % Mandated by managed care contract agreement



### Where does testing go?

- 52% stays within the Pacific NW region
- 48% is sent out of the region
  - 15% to large national reference labs
    - Quest/Nichols Institute California
    - Lab Corp North Carolina
  - 33% to other genetic testing labs